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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,142	11/15/2000	Reinhard Ebner	1488.0630002/KRM	4465 .
7.	590 05/19/2003			
Sterne Kessler Goldstein & Fox PLLC Suite 600 1100 New York N.W. Washington, DC 20005-3934			EXAMINER	
			ROMEO, DAVID S	
·			ART UNIT	PAPER NUMBER
			1647	1 \
			DATE MAILED: 05/19/2003	(0

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
	09/712,142	EBNER ET AL.				
Office Action Summary	Examiner	Art Unit				
•	David S Romeo	1647				
Th MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply in If NO period for reply is specified above, the maximum statutory period with Failure to reply within the set or extended period for reply will, by statute,  - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	i6(a). In no event, however, may a reply be tin within the statutory minimum of thirty (30) day ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35.U.S.C. § 133).				
1) Responsive to communication(s) filed on 24 F	ebruary 2003 .					
2a)⊠ This action is <b>FINAL</b> . 2b)□ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims						
4)⊠ Claim(s) 7 and 24-67 is/are pending in the application.						
4a) Of the above claim(s) <u>7</u> is/are withdrawn from consideration.						
5)☐ Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>24-67</u> is/are rejected.						
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)	-					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.1	5) 🔲 Notice of Informal I	y (PTO-413) Paper No(s) Patent Application (PTO-152)				

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#### **DETAILED ACTION**

The amendment filed February 24, 2003 (Paper No. 10) has been entered. Claims 7, 24-67 are pending.

Election/Restrictions

Applicant's comments regarding the restriction requirement are noted. Although group I in the restriction requirement mailed June 28, 2002 (Paper No. 6) contained claims 1-13, 18, Applicant was additionally required to elect a single sequence within that group. See paragraph no. 2 at page 5 of the restriction requirement mailed June 28, 2002 (Paper No. 6). Applicant elected the nucleotide sequence that encodes a polypeptide comprising amino acids -19 to 231 of SEQ ID NO: 2 (see page 3, full paragraph 1, of the response filed July 22, 2002, Paper No. 7) in response to paragraph no. 2 at page 5 of the restriction requirement mailed June 28, 2002 (Paper No. 6). Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim, in accordance with paragraph no. 2 at page 5 of the restriction requirement mailed June 28, 2002 (Paper No. 6) and with Applicant's election of the nucleotide sequence that encodes a polypeptide comprising amino acids -19 to 231 of SEQ ID NO: 2 (see page 3, full paragraph 1, of the response filed July 22, 2002, Paper No. 7).

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## Information Disclosure Statement

References AS and AT on the information disclosure statement (IDS) filed May 31, 2002 (Paper No. 5) have been considered to the extent possible, but a residue by residue comparison of the sequences listed with presently claimed sequences has not been done.

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### Maintained formal matters, objections, and/or rejections:

### Claim Rejections - 35 USC § 101, § 112

Claims 24-67 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

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Applicant directs the examiner's attention to pages 62-63 where CTGF-3 expression data is presented. Applicant's arguments have been fully considered but they are not persuasive. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information regarding this nucleic acid could be put. An analysis of CTGF-3 structure is merely descriptive information and artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any structure information regarding CTGF-3 could be put.

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Applicant disagrees with the examiner's characterization of Henikoff. Applicant's arguments have been fully considered but they are not persuasive. Henikoff (AT, cited by Applicants) teaches that shared modules in proteins are to be used as guides for further research. It is noted that the instant specification fails to correlate a specific function of CTGF-3 with any given module of CTGF-3, or even with the entire protein. Utilities that require or constitute

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carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Applicant argues that the examiner has not met his burden that one of ordinary skill in the art would reasonably not doubt Applicant's assertion of utility. Applicant's arguments have been fully considered but they are not persuasive. The evidence of record (see the last Office action, Paper No. 8, at page 5, line 7, to page 6, line 7) shows that without some common biological activity for CTGF family members, a new member would not have either a specific and substantial utility or a well established utility relying solely on the fact that it has structural similarity to the other family members.

Applicant makes arguments regarding the assertion of utility and cites documents in support thereof. Applicant's arguments have been fully considered but they are not persuasive.

The specification discloses that it is believed that certain tissues in mammals with various connective-tissue related disorders express significantly altered levels of CTGF-3 protein and mRNA. By "connective-tissue related disorders" is intended any condition, such as cancer, characterized an under- or over-growth of connective tissue cells. See paragraph bridging pages 30-31. However, this paragraph does not indicate whether CTGF-3 protein and mRNA is under-or over-expressed in cancer.

The specification also discloses that the invention provides a diagnostic method useful during diagnosis of cancer, whereby an increase in the gene expression level over the standard is indicative of these diseases (page 31, lines 7-13). However, this is not a specific disclosure that an increase in the CTGF-3 gene expression level over the standard is indicative of breast cancer.

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The specification also discloses that the invention is useful during the diagnosis of the following types of cancer: breast, ovarian, cervical, prostate, bone, liver, lung, pancreatic, and splenic (page 32, last full paragraph). However, this is not a specific disclosure that an increase in the CTGF-3 gene expression level over the standard is indicative of breast cancer. As indicated previously, the specification also discloses that it is believed that certain tissues in mammals with various connective-tissue related disorders express significantly altered levels of CTGF-3 protein and mRNA. By "connective-tissue related disorders" is intended any condition, such as cancer, characterized an under- or over-growth of connective tissue cells. See paragraph bridging pages 30-31. This paragraph does not indicate whether CTGF-3 protein and mRNA is under- or over-expressed in breast cancer. The specification does not state that an increase in the CTGF-3 gene expression level over the standard is indicative of a particular cancer. The disclosure is such that Applicant can hopefully claim utility regardless of any particular under- or over-expression of CTGF-3 associated with any particular disorder or cancer, while at the same time disclosing nothing regarding the particular expression of CTGF-3 associated with a particular disease or disorder. In the absence of a specific disclosure that CTGF-3 mRNA is over-expressed in breast cancer, documents AR15, AS14, AS15, and AT14 do not support Applicant's contention that the claimed invention is supported by either a specific and substantial asserted utility or a well established utility or a credible utility. As noted by Applicant, despite DNA amplification of WISP-2, mRNA expression was reduced in the majority of colon tumors (document AR7), which contravenes the specification's assertion that the invention provides a diagnostic method useful during diagnosis of cancer, whereby an increase in the gene expression level over the standard is indicative of these diseases (page 31, lines 7-13). The disclosure in

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document AN1, that GRFLP appears to play a role in cancer and connective tissue disorders, particularly disorders in which GRFLP is over-expressed, is not a disclosure of a particular disease or disorder in which GRFLP is under- or over-expressed. The present specification says nothing regarding the amplification of the gene encoding PRO261 and, as noted by document AR7, gene amplification is not associated with an increased expression of WISP-2 mRNA. Further experimentation is necessary to attribute a utility to the claimed protein. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated in the context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful completion.").

Claims 24-67 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. As Applicants recognize, a rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 36-46 are indefinite because they recite the term "mature". Applicant argues that the term is clearly defined at page 8, line 12, to page 9, line 28. Applicant's arguments have been fully considered but they are not persuasive. The specification at page 8, line 12, to page 9, line 28, intends the term "mature" to encompass the mature form produced by expression in a mammalian cell. The instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "mature". The metes and bounds are not clearly set forth. It is suggested that the claims recite "the polypeptide lacking its signal sequence".

#### New formal matters, objections, and/or rejections:

### Claim Rejections - 35 USC § 112

Claims 57-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to or encompass a polypeptide having mitogenic activity for connective tissue cells. The family of connective-tissue cells includes fibroblasts, cartilage cells, bone cells, fat cells, and smooth muscle cells. See Alberts (u12), page 1187, full paragraph 1. The mature fat cell cannot divide. See Alberts (u12), page 1181, Figure 22-42. The specification lacks guidance for, and working examples of, a polypeptide that has mitogenic activity for a cell that cannot divide. The skilled artisan is left to fundamentally unpredictable, extensive, random, trial and error experimentation involving the extensive, random, trial and

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error of conditions required to achieve the desired activity. The skilled artisan is left to fundamentally unpredictable, extensive, random, trial and error experimentation involving the extensive, random, trial and error mutation of SEQ ID NO: 2 in order to determine how to make a polynucleotide encoding a polypeptide with the desired activity. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (AT, cited by Applicants) page 1306, column 1, full paragraph 1, or Ngo (v12) page 433, full paragraph 1, and page 492, full paragraph 2. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 57-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claims are directed to or encompass antibodies specific for the polypeptide of SEQ ID NO: 2 that also bind a polypeptide 95% or more identical to SEQ ID NO: 2. The claims encompass antibodies that bind an epitope of SEQ ID NO: 2 that also bind variant epitopes of

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SEQ ID NO: 2. The specification lacks guidance for making, and working examples of, making such cross-reactive variant epitopes. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (AT, cited by Applicants) page 1306, column 1, full paragraph 1, or Ngo (w12) page 433, full paragraph 1, and page 492, full paragraph 2. The skilled artisan is left to fundamentally unpredictable, extensive, random, trial and error experimentation involving the extensive, random, trial and error variation of SEQ ID NO: 2 in order to obtain such cross-reactive epitopes. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 57-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to or encompass a polypeptide having mitogenic activity for the genus of connective tissue cells. The family of connective-tissue cells includes fibroblasts, cartilage cells, bone cells, fat cells, and smooth muscle cells. See Alberts (u12), page 1187, full paragraph 1. The mature fat cell cannot divide. See Alberts (u12), page 1181, Figure 22-42.

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The specification and claim do not indicate what distinguishing attributes are shared by the members of the genus that have the desired activity. The specification and claim do not provide any guidance as to what changes should be made in order to obtain a polypeptide with the desired activity. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, SEQ ID NO: 2 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. One of skill in the art would reasonably conclude that applicant was not in possession of the genus of polypeptides mitogenic for connective tissue cells. One of skill in the art would reasonably conclude that the disclosure of SEQ ID NO: 2 fails to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claims 57-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to or encompass antibodies specific for the polypeptide of SEQ ID NO: 2 that also bind a polypeptide 95% or more identical to SEQ ID NO: 2. The claims encompass antibodies that bind an epitope of SEQ ID NO: 2 that also bind variant epitopes of SEQ ID NO: 2. This is a genus claim. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not

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provide any guidance as to what changes should be made. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, an antibody that is specific for SEQ ID NO: 2 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

### Claim Rejections - 35 USC § 112

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37-39 recite "said polynucleotide" (claims 37, 38) or "the polynucleotide" (claim 39). The antecedent basis for these limitations is unclear because there are three earlier recitation of "polynucleotide", i.e., the polynucleotide in the claim preamble, the polynucleotide in (a), and the polynucleotide in (b), and it is unclear which polynucleotide is intended. The metes and bounds are not clearly set forth.

Claims 57-67 are indefinite because they recite the term "having specificity for".

Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "having specificity for" an artisan

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cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

#### Conclusion

5 No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zhang (w12) teaches that rCop-1 was identified by mRNA differential display as a gene whose expression became lost after cell transformation. Unlike the other members of the CCN gene family, rCop-1 is not an immediate-early gene, it lacks the conserved C-terminal domain which was shown to confer both growth-stimulating and heparin-binding activities, and its expression is lost in cells transformed by a variety of mechanisms. Ectopic expression of rCop-1 by retroviral gene transfers led to cell death in a transformation-specific manner. These results suggest that rCop-1 represents a new class of CCN family proteins that have functions opposing those of the previously identified members. See the Abstract.

A comparison of the present application's CTGF-3 and rCop-1 is provided below:

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O9JHC6
         TD
                            PRELIMINARY:
                                                PRT:
                                                        250 AA.
              01-OCT-2000 (TrEMBLrel. 15, Created)
20
              01-OCT-2000 (TrEMBLrel. 15, Last sequence update)
              01-JUN-2001 (TrEMBLrel. 17, Last annotation update)
              CCN FAMILY PROTEIN COP-1.
              COP-1.
              Rattus norvegicus (Rat).
25
              Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
              Mammalia; Eutheria; Rodentia; Sciurognathi; Muridae; Murinae; Rattus
              SEQUENCE FROM N.A.
30
              MEDLINE=98414629; PubMed=9742130;
              Zhang R., Averboukh L., Zhu W., Zhang H., Jo H., Dempsey P.J., Coffey R.J., Pardee A.B., Liang P.;
              "Identification of rCop-1, a new member of the CCN protein family, as a negative regulator for cell transformation.";
35
                    Cell. Biol. 18:6131-6141(1998).
               [2]
              SEQUENCE FROM N.A.
              Liang P.;
              Submitted (APR-2000) to the EMBL/GenBank/DDBJ databases.
40
              EMBL; AF259981; AAF69011.1;
               InterPro; IPR000867; IGFBP
               InterPro; IPR001211; PLP A2
               InterPro; IPR000884; TSP1
              InterPro; IPR001007; VWFC.
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Pfam: PF00219; IGFBP; 1
           Pfam; PF00090; tsp_1;
           Pfam: PF00093; vwc: 1.
           SMART; SM00121; IB; 1.
 5
           SMART; SM00209; TSP1; 1.
SMART; SM00214; VWC; 1.
           PROSITE; PS00222; IGF_BINDING; 1.
           PROSITE; PS00119; PA2_ASP; UNKNOWN_1
           PROSITE; PS01208; VWFC; UNKNOWN_1.
SEQUENCE 250 AA; 27005 MW; 9A147074626BCA47 CRC64;
10
                             70.6%; Score 1019; DB 11; Length 250;
        Ouerv Match
        Best Local Similarity
                             70.8%; Pred. No. 1.3e-91;
15
               177; Conservative
                                  19; Mismatches
                                                      Indels
               MRGTPKTHLLAFSLLCLLSKVRTQLCPTPCTCPWPPPRCPLGVPLVLDGCGCCRVCARRL 60
      Qу
               MRGSPLIRLLATSFLCLLSMVCAQLCRTPCTCPWTPPQCPQGVPLVLDGCGCCKVCARRL 60
20
               Qу
      Db
25
               CRCEDGGFTCVPLCSEDVRLPSWDCPHPRRVEVLGKCCPEWVCGOGGGLGTOPLPAQGPQ 180
      Qy
               Db
      Qу
               FSGLVSSLPPGVPCPEWSTAWGPCSTTCGLGMATRVSNQNRFCRLETQRRLCLSRPCPPS 240
30
                RGRSPQNSAF 250
      Qv
               | | ||||
RSHSSWNSAF 250
35
       Db
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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

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IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

**BEFORE FINAL** 

(703) 872-9306

AFTER FINAL

(703) 872-9307

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IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO PRIMARY EXAMINER

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MAY 15, 2003